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APPLICATION NO.	FILING D.	ATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/731,302	12/09/20	003	William F. Weitzel	UOM 0321 PUS	3644
22045	7590 0	77/26/2005	•	EXAM	INER
BROOKS KUSHMAN P.C. 1000 TOWN CENTER				JAWORSKI,	FRANCIS J
TWENTY-SECOND FLOOR			ART UNIT	PAPER NUMBER	
SOUTHFIEL	D, MI 48075			3737	

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		<i>\begin{align*} \tau_{\text{\colored}} \</i>					
	Application No.	Applicant(s)					
	10/731,302	WEITZEL ET AL.					
Office Action Summary	Examiner	Art Unit					
•	Jaworski Francis J.	3737					
The MAILING DATE of this communication ap Period for Reply	opears on the cover sheet wi	th the correspondence address					
A SHORTENED STATUTORY PERIOD FOR REP THE MAILING DATE OF THIS COMMUNICATION  - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a re - If NO period for reply is specified above, the maximum statutory perio  - Failure to reply within the set or extended period for reply will, by statu.  Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b).	.136(a). In no event, however, may a reply within the statutory minimum of thirt d will apply and will expire SIX (6) MON ate, cause the application to become AB	eply be timely filed  y (30) days will be considered timely.  THS from the mailing date of this communication.  ANDONED (35 U.S.C. § 133).					
Status							
1) Responsive to communication(s) filed on 22	March 2004.						
3) Since this application is in condition for allow	Since this application is in condition for allowance except for formal matters, prosecution as to the ments is						
closed in accordance with the practice under	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4) ⊠ Claim(s) 1-54 is/are pending in the application 4a) Of the above claim(s) is/are withdrest is/are allowed.  5) □ Claim(s) is/are allowed.  6) ⊠ Claim(s) 1-54 is/are rejected.  7) □ Claim(s) is/are objected to.  8) □ Claim(s) are subject to restriction and	awn from consideration.						
Application Papers							
9)☐ The specification is objected to by the Examin	ner.	•					
10) ☐ The drawing(s) filed on is/are: a) ☐ ac	0) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to th							
Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the l							
		, -, -, -, -, -, -, -, -, -, -, -, -, -,					
Priority under 35 U.S.C. § 119		4404 \ 410 \ 410					
a) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the prapplication from the International Bure  * See the attached detailed Office action for a list	nts have been received. nts have been received in A iority documents have been au (PCT Rule 17.2(a)).	pplication No received in this National Stage					
Attachment(s)	_						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	summary (PTO-413) s)/Mail Date						
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date <u>03222004</u> .	——————————————————————————————————————	nformal Patent Application (PTO-152)					

#### **DETAILED ACTION**

### Specification.

The disclosure is objected to because of the following informalities: Suggest change to -- manometer – spec. page 12 line 20..

Appropriate correction is required.

## Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### I. Excised Specimen Case

Claims 1-2, 4, 7-8, 10, 12, 15, 25-26, 28, 31-32, 34, 36, 39, 41, 43, 46-47, 49-50, 52-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Langwouters et al (Jrnl Biomech. 1984 Vol. 17, of record with applicants' IDS filed March 22, 2004). Using the interpretation that base claim 1 is not limited to in-vivo methodology but extends to include an in vitro investigative method using physiologic pressure levels, the Langewouters et al Fig. 1 apparatus and protocol consists of altering pressures by reducing or increasing wrt normal ranges across the specimen arterial wall, measuring intramural diameter displacement deformation and determining features of the mechanical compliance curve from the results. Since Langewouters et al apply supranormal intra-arterial pressures in the Fig. 3 measurement cycle they necessarily are measuring over a pressure range (supranormal) having a larger pressure-strain relationship than the normal because of the inherent nature of the artery, and may step increment in either direction soas to provide mean or static pressures in a reducing sequence.

Claims 3, 11,27, 33, 35, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langewouters et al as applied to claim 1 above, and further in view of Banks et al (Circulation 7/6/99, of record with the 3/22/04 IDS) or Sarvazyan et al (US5524636) since whereas the former elects to use an x-ray to derive baseline artery

segment diameter (page 427 col. 1 bottom para) it would have been obvious in view of Banks et al page 42 brachial discussion or Sarvazyan et al col. 24 lines 31-45 to use ultrasound imaging since this was a known equivalent for producing artery diameter information.

.Claims 9, 16-19, 22-23, 40, 48, 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langewouters et al as applied to claim 1 above, and further in view of Breul et al (Atherosclerosis 127 (1996) of record in the IDS) since the page 156 Fig.1 graph therein shows that aortic stiffness hence inverse compliance may derive directly from a load-strain curve in the in vitro case. Further, since Bruel et al relate the arterial stiffness associated with aging as commented upon by the former to susceptibility to atherosclerosis, this is an index of how 'disease prone' an arterial segment would be and its health (suppleness) although excised from the body at autopsy.

#### II. In-Vivo Measurements

Claims 1-6, 8-14,16-21,23-30,32-38, 40-45 and 47-54 are rejected under 35

U.S.C. 103(a) as obvious over the combined teachings of Banks et al (see entire article) and Sarvazyan et al (see col. 20 line 3 –col. 24 line 45 with additional note that since the static applied pressure is varied across normal physiologic ranges one necessarily applies first and second mean arterial pressures with differing pressure-strain slopes.)

For simplicity these analogous applied cuff pressure measurement systems are grouped together – Banks et al is more attentive to the transmural pressure vs

displacement relationships; Sarvazyan et al overtly mentions the direct computation of vessel wall strains from the cuff system configuration, see col. 21 lines 6-15.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738

Francis J. Jaworski Primary Examiner

FJJ:fjj

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